IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-567 (CFC)
NATERA, INC.,	)	
Defendant.	)	

DEFENDANT NATERA INC.'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 12(b)(6)

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I. INTRODUCTION

The Supreme Court's test for patentability under 35 U.S.C. § 101 is a simple two-step inquiry: (1) Are the claims directed to a patent-ineligible concept (such as a natural phenomenon)?; (2) If so, do additional non-routine elements transform the claim into a patent-eligible application of the otherwise ineligible concept? *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014). If the final answer is no, then the claims are not patent-eligible. *Id.*

Here, it is undisputed that the circulating cell-free nucleic acids recited in the asserted claims are a natural phenomenon. And the patents repeatedly state that the additional recited techniques for detecting them—genotyping, high-throughput sequencing, and digital PCR—were not only known, but previously used to detect circulating cell-free nucleic acids that correlate with conditions such as cancer or fetal abnormalities. Plaintiffs argue in their Opposition that using these same known techniques to detect circulating cell-free nucleic acids corresponding to a ***different*** condition—here organ transplant rejection—makes the claims patentable. But using conventional methods known to be effective in detecting some natural phenomena (tumor or fetal cell-free nucleic acids) to detect a different natural phenomenon (donor-specific cell-free nucleic acids in an organ transplant recipient) is not patentable.

Natera's Opening Brief demonstrates that the asserted claims are unpatentable using the only evidence that matters at the Rule 12(b)(6) stage: the words and history of the patents and the pleadings. By contrast, Plaintiffs' Opposition relies on nearly 300 pages of extraneous and irrelevant "evidence" and numerous incorrect legal standards to manufacture unnecessary complexity for a straightforward inquiry. For example, Plaintiffs rely on an expert declaration that is procedurally improper, contradicts the words of the asserted patents, and uses conclusions to create the impression of a "fact intensive" and technologically "dense" inquiry unsuitable for early disposition. But Plaintiffs' factually and legally erroneous arguments cannot change the answer to the Section 101

inquiry: Plaintiffs' asserted claims apply conventional techniques to detect the natural phenomena of donor-specific cell-free nucleic acids that arise as a direct consequence of, and correlate to, a patient's body rejecting a transplanted organ.

As discussed below, the Federal Circuit repeatedly has affirmed Section 101 dismissals under Rule 12, including for analogous claims more technically sophisticated than those here. This Court in fact recently held patents invalid at the Rule 12 stage, and should do so here. *In-Depth Test, LLC v. Maxim Integrated, Prods., Inc.*, 2018 WL 6617142, *3-4 (D. Del. Dec. 18, 2018).

II. PLAINTIFFS' EXTRANEOUS EVIDENCE SHOULD BE DISREGARDED

To support their arguments, Plaintiffs rely almost entirely on two irrelevant sources that are not part of the pleadings: (1) a declaration (with exhibits) by Dr. Henry Furneaux, which contradicts the asserted patents; and (2) a misreading of Natera's (not Plaintiffs') patent filings and website. The Third Circuit has made clear that "a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). Indeed, courts routinely reject expert testimony submitted to oppose a Rule 12 motion, including Section 101 motions. *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 755 (Fed. Cir. 2019); *Ass'n of Irritated Residents v. Fred Schakel Dairy*, 2008 WL 850136, at *4 n.4 (E.D. Cal. Mar. 28, 2008). Courts also regularly disregard extraneous patents and advertising materials, like those relied on by Plaintiffs here, in deciding § 101 motions to dismiss. Opp. at 4, 12-13, 15; *O2 Media, LLC v. Narrative Sci., Inc.*, 149 F. Supp. 3d 984, 995 (N.D. Ill. 2016). Here, too, the Court should disregard Plaintiffs' references to these extraneous materials and any arguments based upon them.

III. PLAINTIFFS MISSTATE AND MISAPPLY THE APPLICABLE § 101 LAW

Under the properly applied *Alice/Mayo* test, Plaintiffs cannot demonstrate that the asserted claims are directed to anything beyond conventional techniques to detect the correlation between

donor-specific cell-free nucleic acids in a transplant recipient's circulation and rejection of a transplanted organ. Plaintiffs' Opposition does not even attempt to do so. Instead, Plaintiffs contend that their claims are patentable based on an erroneous application of the two-step *Alice/Mayo* inquiry that finds no support in the law and offer purportedly "factual" assertions that contradict the words of the patents themselves.[1] Plaintiffs' arguments should be rejected.

A. Plaintiffs Misapply *Alice/Mayo* Step One

Alice/Mayo Step One ("Step One") asks whether the asserted claims are directed to a natural phenomenon. *Alice*, 573 U.S. at 217. Here, the parties agree—and the patents themselves expressly recite—that donor-specific cell-free nucleic acids exist in the body of a transplant recipient. Br. at 10-11; Opp. at 5-6, 11; D.I. 11-1, Ex. B at 27:39-40 ('652 patent). The patents also expressly disclose that the amount of those nucleic acids correlates with transplant rejection. Br. at 10-11; D.I. 11-1, Ex. B at 27:61-67 ('652 patent). These nucleic acids indisputably exist irrespective of how or whether they are detected. But Plaintiffs ignore the patents' own descriptions of these natural phenomena, and instead base their Step One analysis on (1) the ***method of detecting*** of the cell-free nucleic acids, and (2) the ***transplant procedure*** prompting their existence. Opp. at 10-13. This is legally incorrect.

Plaintiffs' primary Step One argument is that the asserted claims are not directed to the natural phenomenon of donor-origin cell-free nucleic acids in transplant patients but rather to purportedly "novel processes for detecting" those nucleic acids. Opp. at 15. That is wrong. The Federal Circuit has made clear that the method of detection is immaterial to Step One as "laws of nature exist regardless of the methods used by humans to observe them." *Cleveland Clinic Found. v.*

[1] Plaintiffs' Appendix A is improper attorney argument seeking to analogize the case law to the instant facts in excess of the 20-page limit for an opposition brief pursuant to Local Rule 7.1.3(a)(4). The Court should reject Plaintiffs' further attempt to use Appendix A to argue that claim length is a proxy for patent eligibility, as it is the *Alice/Mayo* test—not the length of the claims—that controls.

True Health Diagnostics LLC, 760 F. App'x 1013, 1019 (Fed. Cir. 2019).

The facts here are analogous to *Cleveland Clinic*, where the patents claimed detecting concentrations of the blood-borne protein Myeloperoxidase ("MPO"), which increase in patients with cardiovascular disease. *Id.* at 1015-17. The *Cleveland Clinic* claims recited techniques to identify blood-borne MPO, such as immunoassays and spectrophotometry, which are as complex (if not more) than the methods claimed here. *Id.* at 1016-17; Br. at 2-4. In holding the *Cleveland Clinic* claims ineligible, the Federal Circuit viewed the recitation of complex but well-known detection methods (immunoassays and spectrophotometry) as mere "draftsman's art," recognizing the claims were improperly directed to natural correlations between MPO and heart disease that exist "regardless of the methods used by humans to observe them." *Id*. at 1018-19.

The same is true here. Donor-specific cell-free nucleic acids in a transplant recipient exist in the recipient's blood and correlate with transplant rejection. Br. at 4-5. These nucleic acids result from biological processes in the transplant recipient's body, and the recited detection methods—genotyping, high-throughput sequencing or digital PCR—do not create them. Rather, they exist irrespective of the detection methodology. *Id*. at 10-11. Plaintiffs' attempt to shift the inquiry to alleged "human-developed techniques of the inventions" thus misses the mark. Opp. at 10-13.

Plaintiffs also argue—again in direct contradiction to the language of the asserted claims—that the patents "are not directed to nucleic acids, any general correlation with disease, or anything else that could be characterized as a natural phenomenon." *Id.* at 11. But the claims themselves establish why this argument is incorrect. For example, Claim 1 of the '497 patent recites "[a] method of detecting donor-specific circulating cell-free nucleic acids in a solid organ transplant recipient[.]" D.I. 11-1, Ex. A at 28:2-3. Claim 1 of the '652 patent recites "[a] method for detecting transplant rejection, graft dysfunction, or organ failure," D.I. 11-1, Ex. B at 27:39-40, by "determining a

quantity of the donor cell-free nucleic acids," *id.* at 27:61-62, "wherein an increase in the quantity of the donor cell-free nucleic acids over time is indicative of transplant rejection, graft dysfunction, or organ failure." *Id.* at 27:64-67. Claims like these that involve "detecting a natural law 'with no meaningful non-routine steps'" are not patent eligible. *Athena Diagnostics*, 915 F.3d at 752 (quoting *Cleveland Clinic Found. v. True Health Diagnostics, LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017)); Br. at 10-11; *infra* § III(B) (showing recited steps are routine).

Plaintiffs further contend that Step One is not satisfied because the claimed methods "are intended to be applied in the most unnatural circumstances—introduction of a foreign organ into a human body." Opp. at 11-12. But Plaintiffs' contention that a transplant is unnatural is irrelevant to Supreme Court precedent establishing that the body's response to a foreign agent is still a natural phenomenon even if the agent is man-made. In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, the Supreme Court invalidated claims reciting the body's response to ***man-made*** thiopurine drugs. 566 U.S. 66, 72 (2012). The *Mayo* Court noted that some patients receiving thiopurine reacted by generating thiopurine metabolites measurable in their blood. *Id.* at 73-74, 77. The Court held that claims directed to measuring those blood-borne metabolites were unpatentable because the body's reaction to thiopurine and the metabolite products thereof were natural phenomena. *Id.* at 77-80. The same is true here. A patient's reaction to a foreign organ—including immune reactions resulting in increased donor-specific cell free nucleic acids—is a natural phenomenon.

Plaintiffs finally argue that the recited creation of "SNP profiles" makes the claims "more specific," and thus not directed to natural phenomena. Opp. at 11. Not so. The claimed "profiles" describe yet another natural phenomenon—nothing more than a selected assortment of naturally occurring genetic variations detected in the sample. Indeed, the patents disclose that "any donor and recipient will vary at roughly three million SNP positions if fully genotyped." D.I. 11-1, Ex. B at

13:42-44 ('652 patent); *id.* at 16:3-7; Br. at 15. The profiles select a number of SNPs where variation between the donor and recipient exists. D.I. 11-1, Ex. B at 13:44-66 ('652 patent). It is well-settled that such compilations of naturally-occurring genetic variations are unpatentable. *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1375-76 (Fed. Cir. 2016) (finding claims directed to analyzing subsets of variations in genetic information unpatentable); *PerkinElmer, Inc. v. Intema Ltd.* 496 F. App'x 65, 66-68, 70-71 (Fed. Cir. 2012) (finding method of measuring levels of a profile of biomarkers from pregnancy to determine risk of Down's syndrome unpatentable).[2]

B. Plaintiffs Misapply *Alice/Mayo* Step Two

In *Alice/Mayo* step two ("Step Two"), courts look for an inventive concept in order to "provide practical assurance that the process is more than a drafting effort designed to monopolize the [natural phenomenon] itself." *Mayo*, 556 U.S. at 77.[3] Courts look for something beyond "routine activity" to transform a natural phenomenon to patent-eligible subject matter. *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 714 (Fed. Cir. 2014). And the Federal Circuit has made clear that there is no "inventive concept" if claims "merely recite the use of … existing … technology" in connection with a natural phenomenon. *Content Extraction & Transmission LLC v. Wells Fargo Bank*, 776 F.3d 1343, 1348 (Fed. Cir. 2014); *Athena Diagnostics*, 915 F.3d at 748.

Beyond natural phenomena, the asserted claims recite nothing more than conventional

[2] *See also Esoterix Genetic Labs. LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349, 359-60 (D. Mass. 2015) (claims directed to correlation of certain nucleotide variances to drug responsiveness); *Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings*, 2014 WL 4379587, at *10 (D. Del. Sept. 3, 2014) (method of analyzing sample to detect the presence of certain genetic variations).

[3] Plaintiffs' effort to replace the Section 101 *Alice/Mayo* inquiry with the obviousness standard under 35 U.S.C. § 103 is contrary to law. Plaintiffs assert that "prior art failures," "long-felt but unmet need," "skepticism of others in the field," and no "reasonable expectation of success" render the asserted claims patentable under Section 101. Opp. at 18-19. But these are issues properly examined when considering obviousness under § 103, not patentability under § 101. *In re Bilski*, 545 F.3d 943, 958 (Fed. Cir. 2008) (reversed on other grounds); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007); *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097-98 (Fed. Cir. 1986).

techniques, such as genotyping, high throughput sequencing, and digital PCR. The patent describes ***all of this*** as "known in the art" to detect conditions such as cancer and fetal conditions. Br. at 12-15; D.I. 111-1, Ex. B at 6:57-7:36 (describing "genotyping," "sequencing," and "presence of sequences differing from a patient's normal genotype … to detect disease" as "known in the art").

Plaintiffs' Opposition focuses on the high throughput sequencing and digital PCR limitations of the asserted claims, explicitly conceding that "high-throughput analysis was known in the art." Opp. at 16. But the thrust of Plaintiffs' Step Two argument is that using these techniques ***to detect donor-specific nucleic acids*** makes them unconventional. *Id*. The Federal Circuit rejected the same reasoning under analogous circumstances in *Athena Diagnostics*, holding that use of known, conventional techniques to observe a natural phenomenon—like the claimed techniques here—is not patentable. 915 F.3d at 749. In *Athena Diagnostics*, the Federal Circuit affirmed a Rule 12(b)(6) order invalidating claims directed to detecting MuSK, a blood-borne antibody appearing in patients with a condition called Myasthemia Gravis. *Id.* at 748, 757. Recognizing the natural correlation between blood-borne MuSK antibodies and disease, the Federal Circuit rejected the plaintiff's arguments that sophisticated but ***conventional*** techniques recited in the claims were sufficient to render the claims patentable. *Id.* at 753-55. *Athena Diagnostics* found that "the claims before us only involve detecting a natural law with no meaningful non-routine steps." *Id.* at 752.

The same is true here. Donor-specific cell-free nucleic acids and their correlation with transplant rejection are a natural phenomenon, and the patents disclose digital PCR and high-throughput sequencing were known and used in the art to detect other natural phenomena, namely circulating or cell-free nucleic acids in oncology or prenatal screening. D.I. 11-1, Ex. B at 6:57-7:36 ('652 patent). As in *Athena Diagnostics*, using those conventional techniques to detect cell-free nucleic acids in an organ transplant context does not give rise to patent eligible subject matter.

Plaintiffs also use Dr. Furneaux's declaration in an effort to manufacture a "question of fact" as to how digital PCR was used in the prior art. Opp. at 17. But Dr. Furneaux's opinions are both procedurally improper and in direct conflict with the words of the patents—which explain that digital PCR was the tool of choice for detecting cell-free nucleic acids, even in ***transplant cases*** as early as 2006. D.I. 11-1, Ex. B at 8:1-8 ('652 patent); Opp. at 16-17; Br. at 12-13.

Plaintiffs also contend that the asserted claims are patentable because the "ordered combination" of the methods makes "the claimed invention as a whole" unconventional. Opp. at 17-18. Plaintiffs again rely entirely on Dr. Furneaux's opinion to support their argument. And, again, Dr. Furneaux's conclusory statements contradict the patents' language. Neither the Plaintiffs nor Dr. Furneaux identify ***any statements in the patents*** that say the "ordered combination" of these routine techniques is unconventional. *Id.* To the contrary, the patents describe well-established use of the precise combination of these techniques, including "genotyping," "shotgun sequencing," and others to do "quantitative assay[s]" for "detecting" cancer, fetal disorders, and other conditions, wherein "[i]n all these applications of circulating nucleic acids, the presence of sequences differing from a patient's normal genotype has been used to detect disease." D.I. 11-1, Ex. B at 6:57-7:36 ('652 patent). Applying these established combinations to detect another natural phenomenon (circulating nucleic acids in an organ transplant recipient) does not make those combinations unconventional.

Like Step One, Plaintiffs fail at Step Two to rebut Natera's showing—based on the words of the patents themselves—that the asserted claims are directed to nothing more than using techniques known in the art for detecting natural phenomena. This should end the inquiry.

IV. PLAINTIFFS' PRAISE OF THE INVENTORS' WORK IS IMMATERIAL

Plaintiffs' Opposition attempts to paint the named inventors as "pioneer[ing]," presumably to imply that their claimed inventions must be patentable and a finding otherwise would be unjust. Opp. at 1, 7. But even if Plaintiffs' characterizations of the inventor's work were deemed true, neither the

amount of research done nor its scientific significance informs the question of patentability. In fact, the Federal Circuit has held that even the most "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Genetic Techs.*, 818 F.3d at 1374 (internal quotations and citation omitted). Rather, it is the *Alice/Mayo* inquiry (which the claims here fail), and not the alleged "genius" of the inventors, that controls.

V. PLAINTIFFS' PREEMPTION AND CLAIMED ADVANCE ARGUMENTS FAIL

Plaintiffs contend that Natera does not show complete "preemption," which according to Plaintiffs is key to the Section 101 analysis. Opp. at 15. Not so. While "preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility." *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1098 (Fed. Cir. 2016). "Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015); *Money Suite Co. v. 21st Century Ins. & Fin. Servs., Inc.*, 2015 WL 436160, at *5 (D. Del. Jan. 27, 2015).

Plaintiffs also argue that Natera did not evaluate the patents' "claimed advance" over the prior art. Opp. at 14. But the only "advance" over the prior art described in the patents is the use of known methods to detect naturally occurring donor-specific cell-free nucleic acids in transplant recipients. As the patents consistently explain, these same known methods were previously used to detect naturally occurring circulating DNA in, for example, pregnant women or cancer patients. *E.g.*, D.I. 11-1, Ex. B at 6:57-7:36 ('652 patent); Br. at 18-19. Where, like here, the "claimed advance" over the prior art is simply a new natural phenomenon observed using conventional methods, the claimed invention is not patentable. *Cleveland Clinic*, 859 F.3d at 1360-61; *XY, LLC v. Trans Ova Genetics, LC*, 333 F. Supp. 3d 1097, 1105 (D. Colo. 2018); *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 2017 U.S. Dist. LEXIS 143434, at *32 (S.D. Cal. Sep. 5, 2017).

Plaintiffs' attempt to rely on *Rapid Litig. Mgmt. Ltd v. CellzDirect, Inc.*, 827 F.3d 1042, 1050 (Fed. Cir. 2016) to salvage their claims also fails, as that case is readily distinguishable and was distinguished based on analogous facts by the Court in *Illumina, Inc. v. Ariosa Diagnostics, Inc.*, 356 F. Supp. 3d 925, 933-35 (N.D. Cal. 2018). Opp. at 13-14. The claimed method in *CellzDirect* resulted in a type of ***unnatural*** composition—a "desired preparation of multi-cryopreserved hepatocytes"—based on an unconventional freeze-thaw cycle method. 827 F.3d at 1048-49. Creating a population of cells resilient to an unnatural laboratory process occurring at very low temperatures is not comparable to detecting naturally occurring donor-specific cell-free nucleic acids. And unlike the claims in *CellzDirect*, these claims do not make anything new from donor-specific cell-free nucleic acids, and use conventional methods to detect them.

VI. PLAINTIFFS' "CLAIM CONSTRUCTION" ARGUMENTS REGARDING THE '652 PATENT ARE A RED HERRING

Natera demonstrated that Plaintiffs have not, and cannot, plead infringement of the elements of the '652 patent claims. Br. at 19-20. Contrary to Plaintiffs' Opposition, claim construction is not required to resolve this issue as the meanings of the terms are plainly discernable from the intrinsic record. *Id.*; Opp. at 19-20; *United States Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). But even if the Court were to construe the claims, the record demonstrates that under any construction—which is an issue of law resolvable here—Natera is not infringing the '652 patent claims. *Id.*

VII. CONCLUSION

For the reasons stated above and in its Opening Brief, Natera requests that the Court dismiss the Complaint in its entirety with prejudice.

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June 24, 2019

CERTIFICATE OF SERVICE

I hereby certify that on June 24, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 24, 2019, upon the following in the manner indicated:

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